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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/038,284	<b>Applicant(s)</b> EHRICHT ET AL.	
	<b>Examiner</b> BJ Forman	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>01/02</u> | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I, Claims 1-19 in papers filed 16 May 2003 is acknowledged. Claims 20-24 are canceled.

Claims 1-19 are pending.

***Specification***

2. The disclosure is objected to because of the following informalities:
  - a. The disclosure is objected to because it contains (on page 6) an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
  - b. The description of the drawing presented on pages 10-11 are not identified as "Brief Description of the Drawings" as required.

See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

Appropriate correction is required.

Art Unit: 1634

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-19 are indefinite in Claim 1 for the recitation “the zone of the detection area” because “zone” lacks proper antecedent basis in the claim. It is suggested that Claim 1 be amended to provide proper antecedent basis.

Claims 2 and 3 are indefinite in Claim 2 for the recitation “the temperature adjustment means” because the recitation lacks proper antecedent basis in Claim 1. It is suggested that Claim 2 be amended to provide proper antecedent basis.

Claims 4 and 5 are indefinite in Claim 4 for the recitation “the temperature adjustment means” because the recitation lacks proper antecedent basis in Claim 1. It is suggested that Claim 4 be amended to provide proper antecedent basis.

Claims 6 and 7 are indefinite in Claim 6 for the recitation “whereby preferably a quadrupole system for inducing an electro-osmotic flow is concerned” because it is unclear what structural limitations, if any, are being described or required by the “preferred” claim language. The recitation is further indefinite because it is unclear what limitations “concerned” imposes on the device.

A narrower range or **preferred embodiment** may also be set forth in another independent claim or in a dependent claim. If stated in a single claim, examples and preferences lead to confusion over the intended scope of the claim. In those instances where it is not clear whether the claimed narrower range is a limitation, a rejection under 35 U.S.C. 112, second paragraph should be made (MPEP § 2173.05(b)).

Art Unit: 1634

Claim 7 is indefinite for the recitation “is realized as gold-titanium electrodes” because it is unclear whether the electrodes are gold-titanium.

Claim 8 is indefinite for the recitations “preferably consist of” and “particularly preferred of” because it is unclear what structural limitations, if any, are being described or required by the “preferred” claim language.

Claim 10 is indefinite for the recitation “preferably” because it is unclear what structural limitations, if any, are being described or required by the “preferred” claim language.

Claim 11 is indefinite for the recitation “the zone of the chip” because the recitation lacks proper antecedent basis in “the zone of the detection area” recited in Claim 1. It is suggested that Claim 11 be amended to provide proper antecedent basis.

Claim 15 is indefinite for the recitation “preferably” because it is unclear what structural limitations, if any, are being described or required by the “preferred” claim language.

Claim 17 is indefinite for the recitation “preferably” because it is unclear what structural limitations, if any, are being described or required by the “preferred” claim language.

Claim 18 is indefinite for the recitation “preferably” because it is unclear what structural limitations, if any, are being described or required by the “preferred” claim language.

Claims 18 and 19 are each indefinite for the recitation “the evaluation of the chip-based characterization” because both “evaluation” and “chip-based characterization” lack proper antecedent basis in Claim 1. It is suggested that Claims 18 and 19 be amended to provide proper antecedent basis.

Claims 18 and 19 are each further indefinite because the claims merely recite forms of detection but do not describe or define any structural limitations. Therefore, it is unclear what, if any structural limitations are being claimed.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6, 8-10, 12-15 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999).

Regarding Claim 1, Lipshutz et al disclose a device for duplicating and characterizing nucleic acids, the device comprising, a chamber body containing an optically permeable chip (i.e. glass, Column 14, line 35-Column 15, line 29) having a detection area and being optically permeable at least at the detection area (i.e. transparent window, Column 19, lines 20-29) wherein the chip is placed and sealed on an optically permeable chamber support (i.e. planar glass support, Column 15, lines 9-34) so that a sample chamber having a capillary gap is formed between the chamber support and the detection area (i.e. the reaction chamber is manufactured into the surface of a first planar member which is then covered by a second planar member providing a gap between the first and second planar members, Column 15, lines 9-34). Lipshutz et al further disclose that samples are put into one reaction chamber of the device and transferred to a subsequent reaction chambers via fluid channels for controlled sample processing, fluid flow and nucleic acid amplification via temperature adjustments (Column 16, lines 12-18; Column 18, lines 26-49; and Column 19, lines 1-15).

Regarding Claim 2, Lipshutz et al disclose the device comprising temperature adjustment means connected with the chamber support and permit rapid heating/cooling of the sample chamber i.e. provide conditions for PCR amplifications (Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41).

Art Unit: 1634

Regarding Claim 3, Lipshutz et al disclose the device wherein the temperature adjustment means are situated on the side of the chamber support facing the chamber body (Column 24, lines 34-63 and Fig 2B #128).

Regarding Claim 4, Lipshutz et al disclose the device wherein the temperature adjustment means are structured such that the optical transparency of the chip remains unaffected i.e. the "heater insert" is disposed on the side of the chamber thereby not affecting the transparency of the chip Fig 2B #106/112 (Column 24, lines 34-63 and Fig 2B #128).

Regarding Claim 5, Lipshutz et al disclose the device wherein the temperature adjustment means comprises micro-structured heating elements i.e. nickel-chromium film (Column 24, lines 53-59) and micro-structured temperature sensors (Column 25, lines 7-41).

Regarding Claim 6, Lipshutz et al disclose the device further comprising systems for mixing the sample without affecting the optical transparency of the chip as illustrated in Fig. 7B (Column 25, line 42-Column 26, line 23).

Regarding Claim 8, Lipshutz et al disclose the device wherein the chamber support and body consist of glass and/or synthetic material and/or optically permeable synthetic materials e.g. nylon, Teflon, topaz, polycarbonate, polystyrene, PMMA and/or polymethane, ethyl acrylate (Column 15, lines 26-58).

Regarding Claim 9, Lipshutz et al disclose the device wherein the chamber support consists of thermally conducting material i.e. the heating/cooling means are embedded within the support which then conducts the heat to the reaction chamber (Column 27, lines 37-47 and Fig. 8 #806).

Regarding Claim 10, Lipshutz et al disclose the device wherein the chip consists of optically permeable materials e.g. glass (Column 15, lines 25-29).

Regarding Claim 12, Lipshutz et al disclose the device further comprising an inlet and an outlet spatially separate from each other i.e. fluid channel #212 is an inlet for reaction

Art Unit: 1634

chamber #214 and fluid channel #216 is an outlet for reaction chamber #214 (Fig. 3 and Column 16, lines 12-18).

Regarding Claim 13, Lipshutz et al disclose the device wherein the inlet and outlet are arranged unilaterally and are separated by a gas reservoir nose i.e. gas permeable membrane to allow escape of accumulated gas (Column 17, lines 28-38)

Regarding Claim 14, Lipshutz et al disclose the device wherein the chamber body is sealingly and unreleasably connected with the chamber support with an adhesive or welding connection (Column 15, lines 20-29)

Regarding Claim 15, Lipshutz et al disclose the device wherein the detection area is configured in the form of spots onto which nuclei acid probes are immobilized i.e. positionally distinct probes (Column 9, lines 30-35 and Column 9, lines 20-29).

Regarding Claims 18 and 19, as stated above under 35 U.S.C. 112, second paragraph, it is unclear what structural components are being claimed. However, Lipshutz et al disclose the device comprising detection means for chip-based characterization (Column 12, line 63-Column 13, line 23).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary



Art Unit: 1634

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) in view of McBride et al (U.S. Patent No. 6,296,752, filed 4 June 1999).

Regarding Claim 7, Lipshutz et al disclose a device for duplicating and characterizing nucleic acids, the device comprising, a chamber body containing an optically permeable chip (i.e. glass, Column 14, line 35-Column 15, line 29) having a detection area and being optically permeable at least at the detection area (i.e. transparent window, Column 19, lines 20-29) wherein the chip is placed and sealed on an optically permeable chamber support (i.e. planar glass support, Column 15, lines 9-34) so that a sample chamber having a capillary gap is formed between the chamber support and the detection area (i.e. the reaction chamber is manufactured into the surface of a first planar member which is then covered by a second planar member providing a gap between the first and second planar members, Column 15, lines 9-34) wherein electro-osmotic flow is provided via electrodes (Column 28, lines 56-67) but they do not teach the electrodes are gold-titanium electrodes. However, electro-osmotic flow provided by gold-titanium electrodes was well known in the art at the time the claimed invention was made as taught by McBride et al who teach that improved electrodes for providing electro-osmotic flow comprise gold and titanium (Column 4, lines 1-16). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the gold-titanium electrodes of McBride et al to the electrodes of Lipshutz et al based on the improved teaching of McBride et al (Column 4, lines 1-16).

Art Unit: 1634

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) in view of Atwood et al (U.S. Patent No. 5,475,610, filed 20 April 1992).

Regarding Claim 11, Lipshutz et al disclose a device for duplicating and characterizing nucleic acids, the device comprising, a chamber body containing an optically permeable chip (i.e. glass, Column 14, line 35-Column 15, line 29) having a detection area and being optically permeable at least at the detection area (i.e. transparent window, Column 19, lines 20-29) wherein the chip is placed and sealed on an optically permeable chamber support (i.e. planar glass support, Column 15, lines 9-34) so that a sample chamber having a capillary gap is formed between the chamber support and the detection area (i.e. the reaction chamber is manufactured into the surface of a first planar member which is then covered by a second planar member providing a gap between the first and second planar members, Column 15, lines 9-34) wherein one zone of the chip is a reaction chamber for PCR (Column 19, lines 1-19) but they do not teach the reaction chamber comprises a conical recess. However, it was well known in the art at the time the claimed invention was made that the preferred surface for PCR reactions comprise conical recesses as taught by Atwood et al (Column 12, lines 28-47). Atwood et al further teach that conical recesses provide very tight temperature control for all samples and within each sample throughout the PCR cycles (Column 12, lines 40-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the conical recess of Atwood et al to the PCR reaction chamber of Lipshutz et al thereby providing means for very tight temperature control for the expected benefit of controlling temperature of each sample throughout the PCR cycles as taught by Atwood et al (Column 12, lines 40-47).

Art Unit: 1634

10. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) in view of Fodor et al (U.S. Patent No. 5,744,101, issued 28 April 1998).

Regarding Claim 1, Lipshutz et al disclose a device for duplicating and characterizing nucleic acids, the device comprising, a chamber body containing an optically permeable chip (i.e. glass, Column 14, line 35-Column 15, line 29) having a detection area and being optically permeable at least at the detection area (i.e. transparent window, Column 19, lines 20-29) wherein the chip is placed and sealed on an optically permeable chamber support (i.e. planar glass support, Column 15, lines 9-34) so that a sample chamber having a capillary gap is formed between the chamber support and the detection area (i.e. the reaction chamber is manufactured into the surface of a first planar member which is then covered by a second planar member providing a gap between the first and second planar members, Column 15, lines 9-34) wherein the detection area is configured in the form of spots onto which nucleic acid probes are immobilized i.e. positionally distinct probes constructed using techniques known in the art (e.g. Fodor et al, Column 9, lines 30-35 and Column 9, lines 20-29). But Lipshutz et al do not specifically teach the probe are immobilized through spacers. However, Fodor et al do teach their probes are immobilized through spacers (i.e. linkers) and they teach a motivation to immobilize through spacers i.e. degree of probe-target binding is dependent on the presence of spacers (Column 18, lines 42-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the spacers of Fodor et al to the immobilized probes of Lipshutz et al to thereby maximize probe-target binding as taught by Fodor et al (Column 18, lines 39-41).

Regarding Claim 17, Lipshutz et al teach the device wherein proteins are immobilized (Column 8, lines 39-42) but they do not teach the detection area comprises probes in the form of protein. However, detection areas (arrays) comprising spots of protein probes were well

Art Unit: 1634

known in the art at the time the claimed invention was made as taught by Fodor et al who teach the peptide array provide a tool for high-density peptide-specific antibody recognition (Column 8, line 61-Column 9, line 30). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the peptide probes of Fodor et al to the detection area of Lipshutz et al to thereby provide for high-density antibody screening for the expected benefits of determining relative binding affinity between a plurality of peptides simultaneously as taught by Fodor et al (Column 2, lines 44-49).


**Conclusion**

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
July 31, 2003